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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,320	01/26/2000	Edward R. Wilcox	MA-32CFD1	8391

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/491,320	WILCOX ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-15 are under consideration in this Office Action. New rejections and new grounds for rejection are stated in the instant Office Action. The rejection under 35 USC 103 stated in the previous Office Action has been withdrawn.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the phrase "hybrid pesticidal protein" renders the claim vague and indefinite since it is uncertain whether the claimed invention is limited to having any pesticidal activity. Clarification is required. Claims 2-15 which depend from claim 1 are also rejected because they do not correct the defect of claim 1. Amending the claim to recite a phrase such as "wherein said protein has pesticidal activity" may overcome the rejection.

For examination purposes, the claims are interpreted as being directed to any protein toxin comprising any pest gut cell recognition portion and any cytotoxic agent.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-15 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

The claims as written do not sufficiently distinguish over nucleic acids, proteins, cells, or

antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "an isolated hybrid pesticidal protein toxin" or "a purified hybrid pesticidal protein toxin". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims that are directed toward any protein toxin of any amino acid sequence/structure and comprises any cytotoxic agent and any recognition portion for any pest gut epithelial cell. The scope of the claim includes many cytotoxic compounds and many protein compounds that recognized any component of any pest gut epithelial cell where the cytotoxic compounds and protein recognition component has widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members is permitted.

The specification only describes a *Bacillus thuringiensis* protein toxin fused to diphtheria toxin A and/or B chains. However, the specification does not provide the amino acid sequences (SEQ ID NOS) of the *Bacillus thuringiensis* protein toxin and the diphtheria toxin A and B chains. The specification fails to provide a written description of additional representative members of the highly variable genus. The specification also does not provide a written description of any pest gut epithelial cell components which are to be recognized by the claimed protein toxin.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear,

concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Amending the claim to recite the specific SEQ ID NOS of the claimed protein components may overcome this rejection.

8. Claims 1-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any protein toxin of any amino acid sequence/structure and comprises any cytotoxic agent and any recognition portion for any pest gut epithelial cell.

The specification provides guidance examples for a *Bacillus thuringiensis* protein toxin fused to diphtheria toxin A and/or B chains. However, the specification does not provide the amino acid sequences (SEQ ID NOS) of the *Bacillus thuringiensis* protein toxin and the diphtheria toxin A and B chains. Furthermore, the specification does not provide guidance for any pest gut epithelial cell components which are to be recognized by the claimed protein toxin

The standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation to make the claimed polynucleotide is undue and outside the scope of routine experimentation since one must screen and search for any protein that recognizes any component of any pest gut epithelial cell, fusing the protein to any cytoxic compound, and determining whether the fusion protein is toxic to any insect. Guidance regarding searching and/or screening for the claimed invention is not guidance for making the claimed invention. Furthermore, it cannot be predicted whether the resulting fusion protein has any toxic activity to any insect since no information is provided by the specification regarding the toxic activity of any protein toxin of any amino acid sequence/structure comprising any cytotoxic agent and any recognition portion for any pest gut epithelial cell.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific SEQ ID NOS of the claimed protein components of the protein toxin. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, and 7-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Fraser *et al.* (US 4,870,023). This reference has been attached to the previous Office Actions.

Fraser *et al.* teach a fusion protein comprising a polyhedrin protein of the *Heliothis zea* nuclear polyhedrosis virus fused to a foreign amino acid sequence (see entire patent); the nuclear polyhedrosis virus polyhedrin protein portion is fused to the heterologous peptide by an amino acid linker (see entire patent and column 22, line 50 to column 25, line 68); and the foreign gene for use with the system include endotoxins of insect pathogens such as the *Bacillus thuringiensis* endotoxin (see entire patent and column 39, line 54 to column 40, line 48), diphtheria toxin (see column 38, lines 53-68), and "enzymes, enzyme inhibitors, insect hormone antagonists, neurotoxins, metabolic inhibitors, insect chemattractants, endotoxins of other insect pathogens" (see column 40, lines 8-42).

Example 10 of the specification states that envelope proteins of *Heliothis zea* nuclear polyhedrosis virus are involved in recognition and that the said proteins can replace the *Bacillus thuringiensis* toxin recognition portion to make the claimed invention. Therefore, in absence of facts to the contrary, the fusion protein containing the polyhedrin protein taught by Fraser et al. inherently has a recognition portion for a pest gut epithelial cell since the reference and the specification both use the same source material, specifically, the proteins of *Heliothis zea* nuclear polyhedrosis virus. Thus, the reference teachings anticipate the claimed invention.

11. Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Herrnstadt et al. (EP213818).

Herrnstadt et al. (EP213818) teach a toxin (M-7) encoded by a toxin gene obtained from *Bacillus thuringiensis* (see entire publication). Thus, the reference teachings anticipate the claimed invention.

12. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Adang et al. (Gene (1985), 36(3), 289-300).

Adang et al. teach a *Bacillus thuringiensis* toxin encoded by a gene from *Bacillus thuringiensis kurstaki* HD-73 (see Abstract). Thus, the reference teachings anticipate the claimed invention.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. The offical fax phone number (703)872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571)272-1600.

CLF

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